K 013955

510(k) SUMMARY

FEB 0 4 2002

J. Morita Manufacturing Corporation's Veraviewepocs Panoramic X-ray Unit

Name of Device and Name/Address of Sponsor

Trade or Proprietary Name:	Veraviewepocs
Common Name:	Panoramic X-ray Unit
Classification Name:	Extraoral Source X-ray System
Product Code:	EHD (Extraoral Source X-ray System)

J. Morita USA, Inc.
9 Mason
Irvine, California USA 92618
Telephone: 949-581-9600
Facsimile: 949-581-9688
Contact Person: Mr. Junichi Miyata, President
Date Prepared: November 20, 2001

Intended Use

The Veraviewepocs is an extraoral source X-ray unit that it used for dental radiographic examination and diagnosis of teeth, jaw, and oral structure by exposing an X-ray image receptor to ionizing radiation.

Technological Characteristics and Substantial Equivalence

The Veraviewepocs includes a base, a support column, a patient frame mounted to the support column, a C-arm assembly, and a control box. The unit weighs approximately 184 kilograms and has dimensions of 235.5 cm (height), 100 cm (width), and 122 cm (depth). The patient frame and the C-arm assembly are mounted to the support column. The control box, which includes operational lights and an emission button, is typically placed in a separate room from the rest of the system. The patient frame includes patient handles for the patient to hold, a chin rest on which to position the patient's head, and temple stabilizers to position the patient's head during the X-ray session. A lip and nose positioner can optionally be used with the chin rest. The C-arm assembly includes a cassette holder to hold an X-ray cassette on one side of the patient's head, an X-ray head on the other side of the patient's head, a Frankfurt plane light beam, a Frankfurt plane light beam knob, a temple stabilizer knob, an image layer light beam, and a control panel. The Frankfurt plane beam, Frankfurt light beam knob, the temple stabilizer knob, and the image layer light beam are used to position the patient's head for optimal X-ray performance. The control panel also is used to position the patient with respect to the C-arm. With the patient positioned within the C-arm, the operator leaves the room and uses the emission button mounted to the control box to expose an X-ray. Pressing the emission button causes the C-arm to rotate around the patient's head while the X-ray

head emits X-rays in the direction of the X-ray cassette, which contains an intensifying screen and X-ray film, to expose the X-ray film.

The Veraviewepocs can be used to take standard panoramic images, pediatric panoramic images, maxillary sinus panoramic images, and TMJ quadruple images (i.e., four views of the TMJ, one each of both sides of the mouth with the mouth open and closed). A different button on the control panel is used to set the parameters for that type of image. The standard panoramic images can be magnified at 1.3X or 1.7X. The pediatric panoramic image has a magnification of 1.3X, reduces the X-ray image emission by 10 to 15 percent relative to the standard panoramic image, and reduces the angle of the C-arm's rotation to better coincide with the smaller size of a child's dental arch. The maxillary sinus panoramic image has a magnification of 1.5X and is used to examine the maxillary sinus and facial injuries. The TMJ quadruple image has a magnification of 1.3X and causes the C-arm to rotate twice - once with the patient's mouth open and once with the patient's mouth closed.

The Veraviewepocs operates in either a high speed radiographic mode or a normal speed radiographic mode, and with automatic or manual exposure. Use in the high speed radiographic mode causes the C-arm to rotate approximately twice as fast as many conventional extraoral X-ray source units, such as the Veraviewepocs, while still using conventional exposure rate factors, such as tube voltage and tube current (amperage). The benefit of operating in this mode is that the radiation exposure time is reduced by approximately 50% and the amount of ionizing radiation received by the image receptor, is approximately 50% less than during operation in the normal mode of operation. This mode is made possible by using a conventional high sensitivity intensifying screen, and results in the image density remaining the same as in conventional or normal modes. The intensifying screen fluoresces in response to the X-ray radiation. A high sensitivity intensifying screen merely fluoresces more, relative to a low sensitivity intensifying screen, when exposed to the same level of X-ray radiation. The X-ray film is exposed to the fluorescence from the intensifying screen to impart the image on the film.

One example of a screen and film combination is a combination of a conventional Fuji Photo Film Grenex HR-12 Intensifying Screen with conventional Kodak T-Mat G film. The Veraviewepocs also can be operated in the normal speed mode and use a normal speed radiographic screens, such as the Kodak Lanex MEDIUM.

When used in the automatic exposure mode, the X-rays passing through the patient are detected by a sensor. The device uses the signal received to control the tube voltage and current with respect to the speed of the film's movement. The objective of operating in this mode is to ensure a high quality image with a consistent level of density for patients varying in size from small children to large adults.

The Veraviewepocs is substantially equivalent to Instrumentarium Corporation Imaging Division's Orthopantomograph OP100 ("OP100"). The Veraviewepocs and its predicate device are both panoramic X-ray units. The Veraviewepocs is substantially equivalent to the OP100 because both devices have the same general intended use, and similar technological characteristics and operating principles. Specifically, the intended use of

the Veraviewepocs is for dental radiographic examination of teeth, jaw, and oral structures by exposing an X-ray image receptor to ionizing radiation. The Veraviewepocs is intended to be operated by physicians, dentists, and X-ray technicians. The intended use of the OP100 is for producing diagnostic X-ray radiographs of dentition, TM-joints, and skull, and has an ortho trans option for producing cross-sectional and lateral images of the dental arch using linear tomographic methods. Although the wording of the two intended uses is not word-for-word the same, the general intended use is the same.

The principal differences in the technological characteristics between the Veraviewepocs and the OP100 are: (1) the availability of operation of the Veraviewepocs at a high speed radiograph mode and the resulting differences in exposure time; (2) the availability of the preprogrammed exposure control on the OP100, which is not available on the Veraviewepocs; (3) the differences in nominal magnifications available to the operator; and (4) the unavailability of the TMJ postero anterior mode on the Veraviewepocs. These differences do not raise any new issues of safety or effectiveness. As such, the Veraviewepocs raises no new issues of safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2002

J. Morita USA
% Mr. William D. Hare
Fish & Richardson, P.C.
601 Thirteenth Street N.W.
WASHINGTON DC 20005

Re: K013955
Trade/Device Name: Veraviewepocs, Model VE
Dental Panoramic X-Ray Unit
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: November 29, 2001
Received: November 30, 2001

Dear Mr. Hare:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013955

Device Name: Veraviewepocs Panoramic X-ray Unit

Indications for Use:

The Veraviewepocs is an extraoral source X-ray unit that is used for dental radiographic examination and diagnosis of teeth, jaw, and oral structure by exposing an X-ray image receptor to ionizing radiation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K013955